



UNITED STATES PATENT AND TRADEMARK OFFICE

CA
UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,134	09/14/2006	Irina Velikyan	PZ0334	7198
36335 7590 12/22/2006 GE HEALTHCARE, INC. IP DEPARTMENT 101 CARNEGIE CENTER PRINCETON, NJ 08540-6231			EXAMINER PERREIRA, MELISSA JEAN	
			ART UNIT	PAPER NUMBER
			1618	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/22/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/552,134

Applicant(s)

VELIKYAN ET AL.

Examiner

Melissa Perreira

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/6/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

The Elander et al. reference (Chem. Soc. Rev. 2000, 29, 239-249) is missing pages 239 and 240. Therefore the reference was not considered in its entirety.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "strong anion exchanger" is a relative term. It is unclear as to what strong anion exchanger is preferred or would be acceptable for use with the present invention.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Griffiths et al. (WO03/059397) in view of the combined disclosures of Gustavson et al. (US 5,607,659) and Yngve (Int. Diss. Abs. 2001, 62, abstract).

3. Griffiths et al. (WO03/059397) discloses a radiolabeling method for the preparation of a NOTA or DOTA (containing N hard donor atoms) labeled ^{68}Ga for use in PET (p18, paragraph 1) and the development of a $^{68}\text{Ge}/^{68}\text{Ga}$ in-house titanium dioxide generator (p7, paragraph 3; p8). The macrocyclic-chelating agent, such as DOTA may be linked to a peptide that can target the site of a disease, thus generating a bifunctional chelating agent comprising a targeting vector which will be site-specific (p9, paragraph 1). The method of producing a radiolabeled gallium complex involves reacting the solution of a peptide labeled macrocyclic chelate with the ^{68}Ga diluted from the $^{68}\text{Ge}/^{68}\text{Ga}$ titanium dioxide generator which can be fitted with an anion-exchange membrane, such as a Q5F cartridge (p12, paragraph 1; p13, paragraph 2; p16, paragraph 2). Griffiths et al. (WO03/059397) does not disclose the synthesis of the ^{68}Ga -DOTA-peptide complex via microwave or a ^{68}Ga -DOTA-oligonucleotide.
4. Gustavson et al. (US 5,607,659) discloses the conjugates or complexes of a directed biodistribution molecule (DBM), one or more bound molecules chelated to a ^{68}Ga , such as an oligonucleotide conjugated DOTA (column 2, lines 11-17; column 10, line 39; column 22, line 25).
5. Yngve (Int. Diss. Abs. **2001**, 62) discloses the preparation of a phosphorothiolated ^{68}Ga -DOTA-oligonucleotide and a ^{68}Ga -DOTA-octreotide (abstract). The abstract also discloses the use of microwave technology for the preparation of other compounds, such as ^{76}Br -labeled octreotide derivatives (abstract; p36, paragraph 2).

Art Unit: 1618

6. At the time of the invention it would have been obvious to produce a ^{68}Ga -DOTA-oligonucleotide complex (see disclosures above) for use as a PET tracer via the production of ^{68}Ga from a $^{68}\text{Ge}/^{68}\text{Ga}$ titanium dioxide generator as disclosed by Griffiths et al. (WO03/059397). The microwave synthesis technique for the method of producing labeled complexes was known by Yngve (Int. Diss. Abs. **2001**, 62, abstract) thus, it would have been obvious to utilize the microwave acceleration technique for a faster, more reproducible preparation of the ^{68}Ga -DOTA-oligonucleotide complex that generates minimal side products. Microwave acceleration techniques have been utilized since the 1980's in a number of production methods for radioactive precursors and radiotracers labeled with positron-emitting nuclides. The microwave method is mostly associated with shortened reaction times and encompasses the microwave conditions of the instant claims. Since the microwave technique was utilized by Yngve (Int. Diss. Abs. **2001**, 62, abstract) it would have been obvious to try all radiotracer labeling reactions with the microwave technique.

Double Patenting

7. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

8. Claims 1,3-7 and 15 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 8-14 of copending Application No. 10/552,206.

This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

9. Claims 1,3-6 and 9-14 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-4,8-13 of copending Application No. 11/358,681.

This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1,2,8-15,18, and 19 of copending Application No. 10/552,206. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of producing a radiolabeled gallium complex of the instant claims encompasses the method for producing a ^{68}Ga -radiolabeled complex of copending Application No. 10/552,206. Both inventions involve reacting a ^{68}Ga radioisotope with a macrocyclic or bifunctional chelating agent via microwave. The microwave technique of copending Application No. 10/552,206 encompasses the microwave conditions of the instant claims. The inventions also include the same peptide or oligonucleotide targeting moiety that may be bound to the chelating agent for site-directed localization. The generation of the ^{68}Ga radioisotope of both applications involves eluting the ^{68}Ga from a $^{68}\text{Ge}/^{68}\text{Ga}$ titanium dioxide generator followed by purification of the ^{68}Ga eluate via a strong anion exchanger comprising HCO_3^- counterions. Therefore, the resulting radiolabeled gallium complex of the instant claims is obviously generated via the synthesis and isolated and would encompass that radiolabeled gallium complex of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 and 8-14 of copending Application No. 11/358,681. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of producing a

Art Unit: 1618

radiolabeled gallium complex of the of the instant claims encompasses the method for labeling synthesis of radiolabeled gallium complex of copending Application No. 11/358,681 since the method steps are identical. Both inventions involve reacting a ^{68}Ga radioisotope with a macrocyclic or bifunctional chelating agent via microwave, using the exact same microwave conditions. The inventions also include a targeting moiety that may be bound to the chelating agent for site-directed localization. The generation of the ^{68}Ga radioisotope of both applications involves eluting the ^{68}Ga from a $^{68}\text{Ge}/^{68}\text{Ga}$ titanium dioxide generator followed by purification of the ^{68}Ga eluate via a strong anion exchanger comprising HCO_3^- counterions. Therefore, the resulting radiolabeled gallium complex of the instant claims is obviously generated via the synthesis and isolated and would encompass that radiolabeled gallium complex of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Perreira whose telephone number is 571-272-1354. The examiner can normally be reached on 9am-5pm M-F.

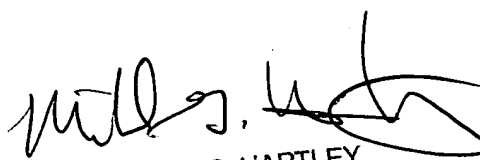
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1618

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MP

December 13, 2006



MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER